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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/584,411	05/31/2000	Richard A. Shimkets	15966-552 (Cura-52)	6088

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EXAMINER

ULM, JOHN D

ART UNIT	PAPER NUMBER
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1646

DATE MAILED: 06/09/2003

DL

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/584,411

Applicant(s)

Shimkets et al.

Examiner

John Ulm

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on _____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-38 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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Claims 1 to 38 are pending in the instant application.

Claims 1 to 38 are objected to as reciting an improper Markush Group. M.P.E.P. 803.02 states that:

“Since the decisions in *In re Weber* **, 198 USPQ 328 (CCPA 1978); and *In re Haas*, 198 USPQ 334 (CCPA 1978), it is improper for the Office to refuse to examine that which applicants regard as their invention, unless the subject matter in a claim lacks unity of invention, *In re Harnish*, 631 F.2d 716, 206 USPQ 300 (CCPA 1980); *Ex Parte Hozumi*, 3 USPQ2d 1059 (Bd. Pat. App. & Int. 1984). Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share a substantial structural feature disclosed as being essential to that utility.”

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I to XXI. Claims 1 to 4, 29 and 32, only in so far as they are drawn to an isolated polypeptide comprising any one of the twenty one amino acid sequences recited therein, classified in class 530, subclass 350. Invention I consists of claims 1 to 4, 29 and 32 only in so far as they relate to an isolated polypeptide comprising the amino acid sequence presented in SEQ ID NO:2. Alternately, invention XXI consists of claims 1 to 4, 29 and 32 only in so far as they relate to an isolated polypeptide comprising the amino acid sequence presented in SEQ ID NO:46.

XXII to XLII. Claims 5 to 14, 19, 30 and 33, only in so far as they relate to an isolated nucleic acid encoding a polypeptide comprising any one of the twenty one amino acid sequences recited therein, classified in class 536, subclass 23.5.

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- XLIII to LXIII. Claims 15 to 18, 31, 34 and 35, only in so far as they relate to an antibody which binds to a polypeptide comprising any one of the twenty one amino acid sequences recited therein, classified in class 530, subclass 387.9.
- LXIV to LXXXIV. Claims 20, 21 and 26, only in so far as they relate to a binding assay employing a polypeptide comprising any one of the twenty one amino acid sequences recited therein, classified in class 435, subclass 501.
- LXXXV to CV. Claims 22, 27, 28 and 38, only in so far as they relate to a method of treatment by administering a compound which binds to a polypeptide comprising any one of the twenty one amino acid sequences recited therein, classified in class 514, subclass 2.
- CVI to CXXVI. Claims 23, 24 and 37, only in so far as they relate to a method of treatment by administering a polypeptide comprising any one of the twenty one amino acid sequences recited therein, classified in class 514, subclass 2.
- CXXVII to CXLVII. Claims 25 and 26, only in so far as they relate to a method of treatment by administering a nucleic acid encoding a polypeptide comprising any one of the twenty one amino acid sequences recited therein, classified in class 514, subclass 44.
- CXLVIII to CLXVIII. Claim 36, only in so far as it relates to a method of genetic analysis by comparatively quantitating a nucleic acid encoding a polypeptide

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comprising any one of the twenty one amino acid sequences recited therein, classified in class 435, subclass 7.21.

The inventions are distinct, each from the other because:

The twenty one different polypeptides of inventions I to XXI, the twenty one different nucleic acids of inventions XXII to XLII and the twenty one different antibodies of inventions XLIII to LXIII are sixty three different chemical compounds each of which can be made and used without the others. These sixty three different compounds lack unity of invention because they do not have a common utility which is based upon a shared special technical feature identified as the basis for that common utility and which is lacking from the prior art.

Each of the twenty one different polypeptides that are inventions I to XXI are related to each of the binding assays of inventions LXIV to LXXXIV and each of the methods of treatment that are inventions CVI to CXXVI as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case each of the binding assays as claimed is materially different from each of the methods of treatment because a binding assay achieves a different objective by employing different methods steps than a method of treatment.

Each of the twenty one different antibodies that are inventions XLIII to LXIII are related to each of the methods of treatment that are inventions LXXXV to CV as product and process of

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use. The inventions are shown to be distinct because each of the claimed antibodies can be employed in the detection of its respective antigen in a sample, which process is materially different from the claimed methods of treatment. Further, each of the methods of treatment, as claimed, is not limited to one which employs a claimed antibody and, therefore, can be practiced with another materially different product.

Each of the twenty one different nucleic acids that are inventions XXII to XLII are related to each of the methods of treatment that are inventions CXXVII to CXLVII and each of the methods of genetic analysis that are inventions CXLVIII to CLXVIII as product and process of use. The inventions are shown to be distinct because the methods of treating, as claimed, achieve different objectives by different methods steps as compared to the analytical methods of inventions CXLVIII to CLXVIII.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any

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amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to John D. Ulm whose telephone number is (703) 308-4008. The examiner can normally be reached on Monday through Friday from 9:00 AM to 5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-4242 or (703) 872-9306. Official responses under 37 C.F.R. § 1.116 should be directed to (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.



JOHN ULM
PRIMARY EXAMINER
GROUP 1800